EXHIBIT B

IN THE UNITED STATES FEDERAL COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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MICHAEL CURRY, : NO. 2:18-CV-00634
Plaintiff :
:
vs. :
:
CARBOFIX ORTHOPEDICS, :
Defendant :

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Oral deposition of DAVID P. POPE, PH.D., taken at DUFFY & FULGINITI, 1650 Market Street, 55th Floor, Philadelphia, Pennsylvania, 19103, beginning at 11:10 a.m., on Tuesday, October 1, 2019, before Karen A. Stevens, Court Reporter and Notary Public, there being present:

A P P E A R A N C E S :

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(It is hereby stipulated by and between counsel for the respective parties that signing, sealing, filing and certification are waived; and that all objections, except as to the form of the questions, be reserved until the time of trial.)

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DAVID P. POPE, PH.D.,

after having been first duly sworn, was examined and testified as follows:

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E X A M I N A T I O N

* * *

BY MS. STUPNEVICH:

Q Good morning, Dr. Pope. My name is Kateryna Stupnevich. I'm with Morris and Mahoney and I represent the Defendant, Carbofix, in this case. We are going to ask you some questions today. Let me know if at any time you want to take a break. The only caveat is we can't have an open question. So you need to answer the question and then we can break afterwards. Okay?

A Okay.

Q Have you ever testified as an expert in

any litigation before?

A Yes.

Q How many times approximately?

A A hundred.

Q When was the last time you testified as an expert in litigation?

A That would have been August, I believe.

Q Of this year?

A Maybe July of this year.

Q Have you ever testified as an expert in connection with a litigation concerning orthopedic medical devices?

A Yes.

Q How many times would you say you testified in those types of matters?

A I'm hesitating there because I looked at numerous devices, but how many of them actually were litigated is another question. But I've certainly looked at probably a dozen orthopedic devices of various kinds.

Q When you say looked at, you mean opined on various issues that may have been involved but not necessarily pertaining to an ongoing litigation?

MR. FULGINITI: Objection to form. You can answer.

THE WITNESS: They were all related, I believe, to ongoing or potential litigation, but whether or not I actually ended up testifying, I don't remember.

BY MS. STUPNEVICH:

Q Okay. Do you recall how many times, if at all, you testified in connection with those types of cases approximately?

A It was just a few. I can imagine probably two or three, something like that, but that's a very rough number.

Q Sure. When was the last time you testified for such litigation?

A That would be probably within the last four years sometime.

Q Have you ever testified as an expert in connection with litigation concerning proximal humerus plates or implants?

A No.

Q What, if anything, did you do to prepare for this deposition?

A I simply reviewed the file.

Q What are the contents of the file that you refer to?

A Certainly the items listed in my report,

which is depositions in my report, the other reports, photographs, Carbofix information, other photographs, reports of the surgery. Probably other things that I can't remember right now.

Q Okay. Have you spoken with anyone, other than Mr. Fulginiti or someone from his office, in preparation for the deposition?

MR. FULGINITI: You mean not in my presence?

MS. STUPNEVICH: Correct.

THE WITNESS: With Anthony Bellots.

MR. FULGINITI: But that was in my presence.

THE WITNESS: Yes, with Mr. Fulginiti.

BY MS. STUPNEVICH:

Q Outside of Mr. Fulginiti's presence have you spoken with anyone else in preparation for this deposition?

A No.

Q I have a copy of your Curriculum Vitae here, which is essentially your resume.

MS. STUPNEVICH: Let's mark that as Pope-1.

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(Whereupon, the above-mentioned

document was marked for identification as Pope-1.)

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BY MS. STUPNEVICH:

Q Doctor, what is your profession?

A I'm a professor of material science at the University of Pennsylvania.

Q How long have you held that position?

A That position I believe I've held for approximately 45 years.

Q How long have you been employed at the University of Pennsylvania?

A Fifty-one years.

Q What positions have you held at the University of Pennsylvania other than your current position?

A Well, I was a junior professor and then an associate professor. So that's the normal thing. And I've had various administrative posts within the university.

Q As a junior professor what subject matter did you teach?

A I taught things generally in the field of material science; thermodynamics materials, materials properties, things related to material

science.

Q And as an associate professor what subject matters did you teach?

A The same.

Q Okay. You mentioned you held various administrative positions there as well. Can you describe some of those for me?

A Yes. I've been a department chairman, I've been an associate dean, I've been the ombudsman of the university and I've been chairman of my own department twice and another department once.

Q And the department chairman was for which department?

A Material science and also for mechanical engineering.

Q Throughout your career have you held any positions at any other facilities or institutions?

A No.

Q Can you please briefly describe your educational background?

A Yes. I have a Bachelor's Degree from the University of Wisconsin, a Master's and PhD from California Institute of Technology and also I served as a post-doctoral research fellow at Caltech.

Q When did you obtain your PhD?

A 1967, as I recall.
Q Sorry. You may have said this. From what Institution?
A California Institute of Technology.
Q You mentioned you were also a post-doctoral research fellow. Where was that work performed?
A Also at Caltech.
Q How long have you held that position?
A How long did I hold it? It was approximately a year and a half, I believe, something like that.
Q I'm going to skip around a little bit, but I want to go over some things on your resume. There's obviously a lot. If you can bear with me and follow along, that would be great. Your resume indicates you have published approximately 200 publications, I believe; is that correct?
A Yes, that's approximately right.
Q When was your most recent publication published?
A That would have been approximately eight years ago or so, maybe ten.
Q Is it fair to say that most of your publications focus on intermetallics, ductility and

thermal properties?

MR. FULGINITI: Objection to form.

THE WITNESS: That's one of the foci, one of the major foci.

BY MS. STUPNEVICH:

Q What would be some of the other foci that you have?

A Things related to behavior of materials at elevated temperature. Maybe that's what you meant by thermal properties.

Q Right. Better way to put it.

A Things related to what we call phase transformation, things related to the changes that occur inside of the material when you do various things to it, and then things related to the strength and toughness of materials.

Q Do you have any publications that focus on orthopedic medical devices?

A No.

Q Do you have any publications that focus specifically on carbon fibro proximal humeral implants?

A No.

Q Skipping along to books and chapters, there's plenty of those, too, when was your most

recent work published?

A You're talking about --

Q In books and chapters that you would have contributed to or written.

A I honestly don't remember, but it looks like it was the early 2000s.

Q Okay. If you had to describe the focus of the books and chapters that you had written for me, how would you describe that?

MR. FULGINITI: Objection to form. You can answer.

THE WITNESS: The focus of those is rather similar to the focus of my general research; things related to strength, toughness, elevated temperature properties, phase transformations.

BY MS. STUPNEVICH:

Q And do you have any books or chapters that focus on orthopedic medical devices?

A No.

Q Any books or chapters that focus on proximal humerus plates?

A No.

Q Turning to your professional activities, it's over a dozen here with the most recent being 1998; is that correct?

A Probably right.

Q Now, is it fair to say that your professional activities focus primarily on the same things as your publications and the books and chapters you've written?

A Yes.

Q Did any of your professional activities focus on orthopedic medical devices?

A No.

Q Did any of them focus on proximal humerus plates?

A No.

Q There is also a section here about research interests and I think you briefly touched upon that already. Can you elaborate a little bit for me as to the type of research that you have focused on throughout your career?

A Yes. Of course the deformation and fracture of the intermetallic compounds, intermetallic compounds are just materials that are comprised of fixed ratios of metals, something like NI3AL. So they have very special properties that I spend a great deal of time studying them. Crystal growth, because when you study those materials you want single crystals so you can study it very

carefully, high temperature fracture, because many of these materials are intended for use at high temperatures, so the question is how do they behave at high temperatures. Other questions related to the question of the protection of the metal by some sort of a ceramic overlayer, you know, aluminum oxide or something like that, and that's determined by the strength of the interface between the two. And then finally many materials become brittle at a low or lowish temperature, and that's called the ductile to brittle transition, and that's very important for the behavior of useful materials.

Q And so now amongst these research interests, have any of them focused specifically on orthopedic implants?

A No.

Q And have any of them focused specifically on proximal humerus plates?

A No.

Q Have you undergone any certifications or training specific to orthopedic medical devices?

A No.

Q Have you undergone any certifications or training specific to proximal humerus plates?

A No.

Q Have you studied any materials or literature that's specific to orthopedic medical devices?

MR. FULGINITI: Objection to form.

THE WITNESS: Certainly the materials themselves related to orthopedic medical devices.

BY MS. STUPNEVICH:

Q What do you mean by that?

A For example, in this matter one of the materials that comes up all the time is the Synthes stainless steel plate, and that is almost certainly a particular grade of stainless steel about which -- on which I've done a fair amount of work, for example. Then also this material for the Carbofix plate is made out of a PEEK carbon fiber composite, and that's another interest of mine that I also study. So I'm aware of the properties and I have studied the properties of these composite materials and how the properties of the materials are determined by the various properties of the individual phases.

Q Okay. Can you identify some of the literature or materials that you have studied in relation to the PEEK carbon fiber composite.

A Well, certainly with regard to this matter I have. There are several papers that were referenced in this matter, and I don't have that at the tip of my tongue, things related to the strength, the bending strength of these composite materials and how they also fail. So those are the main things I have studied.

Q How about outside of this matter? Is there any literature that you can specify for me or any materials that you studied pertaining to the PEEK carbon fiber composite?

A No, I think I have not, not specific to PEEK carbon fiber. Certainly many polymeric carbon fiber composites, but not necessarily that one.

Q Got it. And you referenced for a second there several papers referenced in this matter. Are those things that are referenced in your reports?

A I don't recall if it's referenced in there or not. One of them might be.

Q And we'll get to the report, so we'll talk about that. Have you studied any material or literature specific to proximal humerus plates outside of this matter?

A No -- I should be careful. I mean I have, in your earlier questions about orthopedic devices,

of course I've looked at various plates that have failed and those are the stainless steel variety. I'm not certain that they were proximal humerus plates. They were bone plates.

Q Okay. But again to clarify, the plates that you have looked at with regard to orthopedic devices and failure have been stainless steel plates. Have you looked at any carbon fiber plates?

A I probably have, but I can't quote chapter and verse now.

Q Sure. Do you recall when you would have looked at them, how long ago that might have been?

A That would have been within the last 10 years, because they haven't been around that long.

Q Right. Do you recall any specifics about those carbon fiber plates, what type of plates they were or maybe who manufactured them or anything else?

A No. I'm having a blank on that. I'm sorry.

Q That's okay. Approximately how many carbon fiber plates have you looked at during the last 10 years?

A I think it would be one.

Q And that's outside of the one involved

here?

A Right.

Q Other than what we have already discussed, can you tell me about any other experience that you have with orthopedic implants?

MR. FULGINITI: Objection to form. You can answer if you understand.

THE WITNESS: Well, as we talked about earlier, of course the devices and also the devices used for installing them. I have also analyzed various tools and instruments used by orthopedic surgeons.

BY MS. STUPNEVICH:

Q What kind of devices were those?

A Typically rajas. And those are the most common thing.

Q Do you have any experience with design of orthopedic implants?

A No.

Q Do you have any experience with manufacture of orthopedic implants?

A No.

MR. FULGINITI: You don't mean the design of them. You mean him designing one?

BY MS. STUPNEVICH:

Q Designing or you participating in the design or being consulted on the design, anything like that.

MR. FULGINITI: Again, consulting on the design would implicate everything he's already talked about.

MS. STUPNEVICH: Let me clarify.

BY MS. STUPNEVICH:

Q Have you ever participated in designing an orthopedic implant?

A No. The only designing of orthopedic implants I've been involved in have been student projects where they were given the task of trying to design a particular kind of implant. And then of course students love composite materials and so on and so on.

Q But you've never had, for instance, a manufacturer or retailer or wholesaler of orthopedic implants involve you in the design process, have you?

A I have not.

Q And in that same scope, have you ever been involved in the manufacture of orthopedic implants?

A No.

Q Have you ever performed in or participated in any type of bench testing that pertains to orthopedic implants?

MR. FULGINITI: Objection to form.

THE WITNESS: The only testing I've been involved in is analysis of implants that have experienced difficulties, problems, broken, that kind of thing, corroded.

BY MS. STUPNEVICH:

Q Okay. So similarly, is it fair to say that you've never participated in or been involved in any clinical trials pertaining to orthopedic devices?

A That's correct.

Q And any other studies relating to orthopedic devices other than maybe something that's after the fact when it's already dealing with a fracture?

A That's correct.

Q Now, other than what we are already discussed, can you tell me about any other experience that you have with proximal humerus plates?

MR. FULGINITI: Objection to form. You can answer.

THE WITNESS: I think we have covered my experience.

BY MS. STUPNEVICH:

Q Okay. So again, no participation in or involvement in design of proximal humerus plates?

MR. FULGINITI: Same objection.

THE WITNESS: Not with manufacturers, as we discussed earlier.

BY MS. STUPNEVICH:

Q And by extension, no involvement in the actual manufacture of proximal humerus plates, right?

A That's correct.

Q And also no involvement in any type of bench testing or clinical studies or other trials pertaining to proximal humerus plates?

MR. FULGINITI: Same objection.

THE WITNESS: Again, related to the manufacture or qualification of these devices.

BY MS. STUPNEVICH:

Q Sure. Dr. Pope, do you believe you're qualified to ascertain fracture initiation?

A Yes.

Q Explain.

A That's what I do for my life.

Q Okay. Do you believe you're qualified to do so specifically with regard to proximal humerus plates?

A Certainly with regard to carbon fiber polymeric composite materials, yes.

Q Explain to me what makes you qualified in that area, if you don't mind.

MR. FULGINITI: Objection to the extent that it calls for a legal conclusion, but you can go ahead and answer.

THE WITNESS: Okay to answer?

MR. FULGINITI: Yes.

THE WITNESS: This composite material, this PEEK carbon fiber composite, is just one example of a polymeric material that is strengthened with fibers. There is a whole universe of such materials, and of course that's a very important universe of materials that people like me are very aware of and study and think about a great deal, and study how the -- what the failure processes are.

BY MS. STUPNEVICH:

Q And which of your publications or your work deals specifically with PEEK material?

MR. FULGINITI: Which of his publications?

MS. STUPNEVICH: Either publications or books or chapters that deal specifically with the PEEK material.

MR. FULGINITI: Objection to form.

THE WITNESS: None of them.

BY MS. STUPNEVICH:

Q Okay. Dr. Pope, do you hold any professional engineering licenses or certifications?

A No.

Q Do you believe you can opine on the cause of fracture in this case with any degree of engineering certainty?

A Yes.

Q Dr. Pope, have you ever met Mr. Curry?

A Mr. Curry?

Q Yes, the Plaintiff.

A No, I have not.

Q Have you ever spoken with him?

A No.

Q Let's get to more of the substantive area of questioning pertaining to what's in your report if that's okay. Did there come a time where you inspected the proximal humerus plate involved in this case?

A Yes.

Q Do you recall when that inspection took place, ballpark?

A No, I don't. But it was on the day that I met you, whenever that was.

Q So for the record, it was around March of 2019. Do you recall where this inspection took place?

A Yes. That was at Micron Laboratories in Wilmington, Delaware.

Q Tell me in your own words, if you don't mind, what did the inspection entail?

MR. FULGINITI: Objection to form. It's overly broad, but you can answer.

THE WITNESS: First the inspection entailed looking at the subject broken plate, photographing it, measuring it in detail, comparing that plate to an undamaged exemplar plate, and then examining the plate in a microscope, looking in detail at the cracks and fracture pattern, and then cutting a sample from the end, the proximal end of the plate, for examination in a cross section in a metallographic sample.

BY MS. STUPNEVICH:

Q Okay. Did you perform any radiography on

the involved plate or exemplar plate?

A Yes, we did. We did an X-ray of the subject plate and the exemplar plate.

Q What was the purpose of that?

A Simply to confirm what we thought was in there, namely the tantalum wire and so on.

Q What did you believe the significance of the tantalum wire to be, if anything?

A Its purpose, I believe, is simply to be a radio -- an X-ray opaque portion of the plate so it can be seen in radiographs.

Q Was there any other objective to performing the radiography?

A No, not that I can recall anyway.

Q The microscopy that was performed, was that in regard to the involved plate or the examplar plate or both?

A Both, but mostly the involved plate.

Q What was the purpose of that?

A To study the cracks in the plate, to determine the origin of the cracks and to get an understanding of the numbers and the density of those cracks.

Q Other than what we discussed, was there any other testing performed on the involved plate?

A I don't think so, but I might think of other things as we go along.

Q And now with regard to the exemplar, was there any other testing performed on that?

A No, I don't think there was any testing performed on the exemplar other than looking at it and photographing it.

Q Was the exemplar looked at under a microscope, if you recall?

A Yes, I believe it was.

Q Were there any portions of the exemplar that were cut away for testing like what was done with the involved plate?

A I believe not.

Q You produced a report that documented your findings and conclusions following this inspection, right?

A Yes, I did.

Q Let's mark that and go through it.

MS. STUPNEVICH: Mark this as Pope-2.

* * *

(Whereupon, the above-mentioned document was marked for identification as Pope-2.)

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BY MS. STUPNEVICH:

Q Dr. Pope, feel free to refer to that as you need. I'll ask you some questions about the findings of your inspection and what's in the report. Did you note any wear patterns in the screw holes of the involved plate during the inspection?

A Yes, I did.

Q Can you describe those wear patterns for me?

A There were two kinds of wear patterns in the screw holes. One is the screw holes through which the fracture passed. That's quite a mouthful. The screw holes that the crack went through. And those screw holes were severely rubbed. They were rubbed smooth. There was rather little detail in the protruding portions of that. The second wear comes from the screws that went into those screw holes, and those threads were deformed by the screw heads.

Q If you were to turn to Figure 15 on Page 17 of your report, and then also Figure 16 which is on Page 18 of the report, is that what you're referring to here, the two different types of screw hole threading?

A Yes, Figure 15 shows threads that were

damaged and Figure 16 shows threads that were undamaged because no screw went into that hole.

MR. FULGINITI: Just to be clear, that's not all the exhibits that referred to that.

MS. STUPNEVICH: Sure.

BY MS. STUPNEVICH:

Q If you turn to Figure 15, Dr. Pope, what would cause these type of wear patterns?

MR. FULGINITI: Objection to form.

THE WITNESS: Well, two things. First, in the upper conical portion of the hole, as you can see, there is an area that is a bit rough. And that is almost certainly the result of the screw having been inserted at a slight angle and the head of the screw rubbing against one portion of the hole. The wear patterns in the threads themselves is simply a result of the fact that the hole was pre-threaded, but the threads in the hole don't necessarily match up to the threads that are eventually produced in the bone, and so they have essentially become cross-threaded.

BY MS. STUPNEVICH:

Q Okay. And with regard to what you had mentioned about the wear pattern where the screw's

being inserted and it's being done on an angle and, therefore, damaging that area --

MR. FULGINITI: He said slight angle, to be clear.

BY MS. STUPNEVICH:

Q Aside from the visual inspections, what tests have you done to determine the origin of that wear pattern?

MR. FULGINITI: Objection to form.

THE WITNESS: Only the visual and microscopic examination.

BY MS. STUPNEVICH:

Q And what is the basis for your opinion as to that origin?

A Simply that the damage follows a helical path that can only be made by a screw thread, and only a screw went into that hole. That was one of the holes through which a screw was inserted.

Q Is it conceivable that this damage could have occurred while the screw was being explanted?

A No. The screw follows the threads that were produced when it was implanted and, therefore, when it's explanted it would just follow that same path.

Q Okay. What type of literature, if any,

did you rely on in forming this opinion with regard to the wear pattern?

MR. FULGINITI: Objection to form. You can answer.

THE WITNESS: I think that I didn't depend on any literature. I relied on my experience about fasteners and threaded fasteners in particular.

BY MS. STUPNEVICH:

Q So in other words, is it fair to say that based upon just the visual alone you're under the opinion that you can determine the origin of these patterns and what caused them?

A Yes, visual and microscopic visual, yes.

Q Okay. Were there any other sources that you had consulted in drawing this conclusion pertaining to these wear patterns?

A No.

Q Now, is it conceivable that these wear patterns could have resulted from just ordinary movement over time of the arm?

A No. Such movement would break away the threads. It wouldn't cross-thread the threads.

Q You mentioned that the explant of the screw wouldn't create a cross-threading either?

A No. It was already cross-threaded during the implant, or I should say implant going in, and, therefore, when going out it would follow that same threaded pattern.

Q Is it not possible for a screw to create a cross-thread when it's being removed rather than when it's being inserted?

A No. That would be very, very unusual.

Q But it's possible?

MR. FULGINITI: Objection to form.

THE WITNESS: I have never seen it. But I don't think it's possible, but I can't say it's impossible.

BY MS. STUPNEVICH:

Q Okay. Other than what we have discussed, can you, with a reasonable degree of certainty, rule out any other possibilities for what would have created this wear pattern?

MR. FULGINITI: Objection to form.

THE WITNESS: I believe that that is -- what I just said is true to a very high degree of engineering certainty.

BY MS. STUPNEVICH:

Q But other possibilities, such as maybe the couple of things I mentioned or maybe a few other

causes are something that could have possibly created this as well.

MR. FULGINITI: Objection to form. What are you talking about? He's told you the one and only way he knows --

MS. STUPNEVICH: If he understands the question, let him answer.

THE WITNESS: As I said earlier, I cannot think of another way that you could produce that wear pattern, but I will not definitely rule out any other possibility. But I have never seen one.

BY MS. STUPNEVICH:

Q Got it. Okay. Do you believe that these wear patterns in the screw holes are indicative of the plate's overall bending strength or do you think that there is a relation between the two?

A Yes.

Q What do you believe that relation is?

A We determined that in these areas where the threads are damaged by the screw threads, that the existing threads are subsequently damaged by the screw. Then we find in those same areas substantial numbers of cracks. And those cracks then grow under the load and greatly reduce the strength of the

plate.

Q And what testing did you do to arrive at that conclusion?

A What?

Q What testing did you perform to arrive at that conclusion?

A It was the cross sectional examination of the device.

Q Can you elaborate on that for me and let me know more about what that entailed?

A Yes. To see the cracks in the plate you have to find a way to look inside the plate, which of course is very difficult. So instead, one cuts a cross section through the threaded hole and then you prepare the surface very carefully so it's smooth and scratch-free and so on. And then you look at the threads in cross section across the hole. And then the cracks become easily visible.

Q Now, was a cross section cut from the exemplar? I believe you said no earlier, right?

MR. FULGINITI: Objection to form.

THE WITNESS: From the -- excuse me?

BY MS. STUPNEVICH:

Q From the exemplar.

A No. It was cut from the subject.

Q In order to make a determination concerning the cracks and how that relates to the strength of the plates, would there not need to be some sort of comparison involved, that is what the cross section looks like from one subject to what it might look like against another subject?

A I don't think that's necessary in this case, because the subject plate had literally dozens and dozens of cracks in it, whereas the examplar are visible on the surface of the plate, and the exemplar plate had no cracks whatsoever visible in it. And I think it is a reasonable assumption that the examplar plate was crack free.

Q Okay. Now, with regard to this opinion that we were just talking about, did you rely on any literature in support of that or was this based on the testing you've done and your own experience?

MR. FULGINITI: Objection to form.

THE WITNESS: Two things. One is seeing the cracks themselves and that's a standard metallographic practice. And there is a long literature on that, but it's just a standard procedure. And then the question of what effect do such cracks have on the mechanical performance of a device. And there is a huge

literature on that subject as well, particularly in the fatigue literature.

BY MS. STUPNEVICH:

Q What literature, if any, did you consult in this case with regards to formulating an opinion on what effects the cracks here had?

A Yeah. I didn't specifically consult any literature, because I'm familiar with it and have worked with it for years.

Q Is there any literature that you can recall off the top of your head that would have been pertinent in this case that you know that applied here?

A Oh my. There are books and books written on the effects of preexisting cracks on the fatigue properties of all kinds of different materials. And now you want me to give a specific reference?

Q If you can remember.

A If I can remember, but of course I can't right now.

Q That's okay. Are there any other sources other than what we talked about that you consulted in concluding that there was a connection between the wear patterns in the screw holes and the plate's overall bending strength?

A No. I think those were the important features.

Q Now, to focus more on those cracks that we had discussed and the substantial wear on the fracture surface, if you can turn to Figure 18 on Page 20 of your report, and you can also take a look at Figure 19 on Page 21. What is identified here with circles and labeled as humerus cracks, is that what you're referring to when you talk about the cracks with substantial wear on the surface of the plate?

A These are cracks that resulted from other effects on the plate. The plates -- the cracks that I'm referring to are the cracks that are very close to the threaded holes and are down inside the plate.

Q Is there a better -- looking through these figures and images, is there a better picture that identifies the cracks that you're referring to?

MR. FULGINITI: Do you mind if I step out for a second while you're doing that?

* * *

(Whereupon, a brief recess was taken.)

* * *

THE WITNESS: In answer to your question, Figures 34 through 41 on Pages 35 through 42 of

my report.

BY MS. STUPNEVICH:

Q Okay. And within those figures can you point out to me exactly what you mean when you talk about substantial cracks or where in the image you're referring to?

A Yes. Probably the best place to start is on Page 38 in Figure 37. I think the cracks there are quite obvious. And then they're enlarged and you can see the smaller cracks in Figure 38 on Page 39.

Q Okay. And so the figures that you're pointing to, these are the microscopic images of essentially 35, am I correct, that area where the plate had separated?

A Yes. These are the microscopic images of Figure 35 -- yes. Yes, they're the little red dotted squares that show where those photographs were taken in Figure 35.

Q What is unusual about these cracks to you that would signify that has some sort of effect on the overall bending strength?

MR. FULGINITI: Objection to form. You can answer.

THE WITNESS: There is nothing unusual

about these cracks. They behave like any other crack does, and that is that when a load is applied to a material that contains a crack, that the stresses, the tendency for the material to break at the very tip of the crack, is hugely magnified and the crack wants to grow and they do grow. And then once the crack is there they will grow relatively rapidly, whereas if there is no preexisting crack, then you have to form a crack, and that's much more difficult. So a crack grows easily, but it nucleates, it forms, with difficulty.

BY MS. STUPNEVICH:

Q And your testimony is that these were preexisting cracks?

MR. FULGINITI: Preexisting? Objection to form.

THE WITNESS: These were cracks that were existing once the screw was inserted in the hole.

BY MS. STUPNEVICH:

Q And how do you know that? What is your basis for that opinion?

A Because the hole is so badly deformed and damaged and you can see that the cracks come from

those damaged areas of the hole.

Q Can we look at Figure 18 for a second?

A Figure 18.

Q Yes, on Page 20.

A Okay.

Q Did you examine or inspect the large holes that are on the left side and on the right side of the plate?

A I believe I did. And as I recall, those -- yes, I looked at all the holes and those holes, as I recall, did not have screws in them.

Q Okay. Did you find those holes to have any type of damaged threading at all?

A No, I did not.

Q Can you take a look at Figure 17, which is on Page 19.

A (Witness complies.)

Q Having inspected this part, can you identify for me which of the holes had screws in them?

A Yes, I can. Give me a moment.

Q Take your time.

A So referring to Figure 17, which is the same surface as is viewed in Figure 8, and so in figure 8 if we look at the examplar plate, then

there are screws in holes number 1, 2, 3, 4 and 5.

Q Okay. And now if we were to utilize the same numeration for the involved plate, did you inspect all of those screw holes?

A Oh, yes.

Q And which screw holes did you find damaged worn threads in?

A In the holes in which screws had been inserted.

Q Was that in each of the holes in which screws had been inserted?

A Yes. There were varying levels of damage, but, yes, in all of them.

Q If we are looking at the examplar plate, it looks like there were screws inserted in 1, 2, 3, 4 and in addition to 5, right?

A Yes.

Q So then on the involved plate you have found damage in 1, 2, 3, 4 and 5?

A Yes. But we did cross sectional examination, that is to say we did the destructive examination of hole number 1, as I recall, but let me double check that. No, it was hole number 2 was sectioned.

Q You had testified earlier that the cross

sectional testing that you performed is what led you to conclude that the wear patterns were connected to the strength of the plate; is that right?

MR. FULGINITI: Objection to form.

THE WITNESS: The wear patterns were connected to the cracks in the plate, and the cracks in the plate are related to the strength of the plate.

BY MS. STUPNEVICH:

Q Okay. Now, seeing as how the cross section was taken from a place other than the site of the fracture, can you explain to me how you've arrived at that conclusion?

A The conclusion being that the site of the fracture was also compromised by the same mechanism?

Q Right. I guess my question is, if you're taking a cross section from a different location, what is the basis for drawing that conclusion as to another location?

A Well, of course we looked very carefully at the screw threads in the subject plate in hole number 5, which is the one where the crack passed through, and we find that A, the surface looks exactly the same as in the other cases, and B, we found that there were cracks coming out of the

damaged hole as well. And so we see the same thing that we saw in the other holes.

Q But the other holes did not experience fracture?

A They did not. That's correct.

Q If we can go back to Figure 17 on Page 19, you've identified in your report numerous cracks which appear to be on the surface of the plate, not inside of the screw holes. That's what's circled here?

MR. FULGINITI: Objection to form.

THE WITNESS: That's right. They're on the surface, but they extend into the screw holes, yes.

BY MS. STUPNEVICH:

Q What's the significance of this, in your opinion?

A These cracks are not the result of inserting screws in the screw holes. I'll put it a different way. These cracks were not formed by the threads when the screws were put into the screw holes. These cracks were formed by twisting of the plate when it was screwed down in place on the bone.

Q How do you know that?

A Because that's the only way that such a

stress could be applied to this plate.

Q Is it conceivable that these cracks were formed just as a result of ordinary movement once the plate was attached to the bone?

MR. FULGINITI: Objection to form.

THE WITNESS: I seriously, seriously doubt that.

BY MS. STUPNEVICH:

Q Is it conceivable that these cracks were maybe formed during the explant of the plate?

A No.

MR. FULGINITI: Objection to form.

THE WITNESS: Definitely not.

BY MS. STUPNEVICH:

Q And why do you say that?

A During the explant the screws are just taken out and the surgeon reaches in with forceps and lifts it out of there. There's photographs showing him doing that.

Q What about these cracks makes you conclude that they only could have been formulated during the implant when force was utilized to screw in the plate?

A The plate is designed to take bending stresses, that is to say to be bent along its

length, and, therefore, the stresses that result from that bending point in the direction along the length as well. These cracks were formed by stresses that point 45 degrees away. They're lateral stresses that formed that. And the bending stresses would not, A, produce that kind of a direction and, B, the bending stresses are zero at the end of the plate, whereas the cracks run all the way to the end of the plate.

Q So if I understand correctly, is it really the direction of the cracks that's leading the basis for your opinion? In other words, had the cracks been going in a different direction would that change your conclusion?

MR. FULGINITI: Objection to form.

THE WITNESS: It's the direction of the cracks and the position of the cracks.

BY MS. STUPNEVICH:

Q Position meaning their location relative to the screw holes?

A No. Relative to the end of the plate, for example, in Figure 19.

Q Elaborate on that for me. What is the significance of them being towards the end of the plate?

A Well, as that figure points out, the major stresses applied to this plate are these bending stresses we are talking about, the stresses that the manufacturer applies when they do the fatigue testing and so forth, the fatigue and strength testing on the plate. But those stresses must be, absolutely must be zero, at the end of the plate. There is no stress at the -- bending stress at the end of the plate. And, therefore, if cracks exist at the end of the plate they can only be the result of some stresses from another source.

Q Okay. Is there -- can these cracks be explained by any other cause except possible exertion of force during implantation?

MR. FULGINITI: Objection to form.

THE WITNESS: That's the only one that makes physical sense.

BY MS. STUPNEVICH:

Q Okay. You also note in your report severe delamination between layers of carbon fibers resulting from large cracks. Do you mind going through some of these figures for me and pointing me to what you're referring to when you say that?

A Yes.

MR. FULGINITI: Yes, you mind?

THE WITNESS: Sorry. Well, referring to Figure 19, since we are there, all of those cracks show delamination between the matrix and the carbon fibers, because the carbon fibers run parallel to those cracks. So a fiber reinforced material like this product is very strong parallel to the fibers. It's like wood. Wood is very strong parallel to the grain. This material is very strong parallel to the fibers. But perpendicular to the fibers, like perpendicular to the grain with wood, it's much weaker.

BY MS. STUPNEVICH:

Q And how did you determine the fiber direction?

A Because you can see that.

Q Point me to it. Explain to me what you mean.

A You need to look at higher magnification to do that.

Q Do we have any figures that would show us the magnification?

A I think not, no.

Q What makes you say that the delamination was caused by cracking?

A I'm sorry, what makes me?

MR. FULGINITI: Objection.

BY MS. STUPNEVICH:

Q What makes you say that the delamination between the layers of the carbon fiber was caused by cracking necessarily?

MR. FULGINITI: Objection to form.

THE WITNESS: Well, there's only two choices, right? Either the layers were never properly joined together in the first place, which I think is not credible, or B, they cracked apart at some later time. And delamination is the easiest form of cracking in a material like this.

BY MS. STUPNEVICH:

Q What other forms of cracking are there in materials like this?

A You could have cracking perpendicular to the fibers, and there are examples of that as well. Those are particularly damaging.

Q What is that significant of?

A Because they -- those cracks are driven by the maximum stress, maximum bending stress. So once they get started, they can do a great deal of damage.

Q Wear on the plates are those perpendicular cracks that you're referring to?

MR. FULGINITI: You're asking him to find an exhibit?

BY MS. STUPNEVICH:

Q If you can, yes.

A Well, for example, in Figure 15 on Page 17, in the area where we were talking about the damage to the top of the screw hole, there is a white line that extends more or less straight up on the top of the plate, and that's one such crack.

Q So the cracks that are perpendicular are the ones where the plate is undergoing the most stress?

A That's right.

Q Did you see any such cracks in hole number -- what I'm going to refer to as hole number 5 in the plate based upon the numeration on the exemplar from Figure 8?

MR. FULGINITI: Objection to form.

THE WITNESS: There are quite a lot of them, but there is only one that I can point to that is visible in these figures. But they would be visible in other figures that are part of the data file. But if you refer to Figure

10, there are cracks that -- there is a crack visible that emanates out of the lower partial hole there. And that is one such crack.

BY MS. STUPNEVICH:

Q If these perpendicular cracks are indicative of the areas where the plate has undergone maximum stress, wouldn't it follow that a fracture would likely occur in that area?

MR. FULGINITI: Objection to form.

THE WITNESS: Yes. And it did, yes.

BY MS. STUPNEVICH:

Q But yet we were looking at, for instance, Figure number 15, where we have that type of perpendicular crack within the screw hole, but this is not where the fracture site was.

MR. FULGINITI: Objection to form.

THE WITNESS: I see what you mean. There are two factors that determine how rapidly the crack grows. One is if you have a preexisting crack it really wants to grow. That's the first thing. But the stress in the device is not uniform and the stress is most highly concentrated in the area where it actually fractured. So the short crack that I showed you, in Figure 15 I think it was, is in an area

where the stress is substantially lower than it was in the area shown in Figure 10.

BY MS. STUPNEVICH:

Q With regards to the delamination between the layer of carbon fiber, can you go over the type of testing that you did to determine the origin of that delamination?

MR. FULGINITI: Objection to form.

THE WITNESS: Well, again, referring to Figures 37 and 38 on Pages 38 and 39 of the report, for any kind of a fracture and cracking analysis, the purpose of analysis is to see the cracks. If something is broken it's possible that it's broken but there are no short cracks remaining in the material. That means one large crack went through or it broke by some other mechanism. In this case the area surrounding this hole that was sectioned is just riddled with cracks. And these cracks, if they have an appropriate stress about them, will propagate very quickly.

BY MS. STUPNEVICH:

Q So to go back to my question, as far as the tests that were done to determine the origin of this, was it just the microscopic imaging?

A Yes.

Q And was there any literature that was consulted in formulating your opinions on this issue?

A Well, again, I'm referring to the vast literature that exists in material science about the effects of cracks on particularly the fatigued properties of the materials. So that's the crux of the entire field, is to find the cracks, to follow their progression, and see how fast they move.

Q But you didn't consult anything specific, any specific materials?

A No. I'm so familiar with it.

Q Okay. Is it conceivable that maybe there is another explanation for the delamination? For instance, could it be that the carbon fiber layering that you talked about is something that's common to the PEEK carbon fiber composite material?

MR. FULGINITI: Objection to form.

THE WITNESS: I don't understand the question. Are you saying that possibly when the carbon fiber reinforced composite is manufactured, that it is manufactured with preexisting cracks?

BY MS. STUPNEVICH:

Q No. Let me rephrase my question. The delamination that you're referring to, is that something that may be specific to carbon fiber PEEK material in general, as opposed to say titanium or stainless steel?

MR. FULGINITI: Objection to form.

THE WITNESS: As opposed to what?

BY MS. STUPNEVICH:

Q Titanium or stainless steel.

A Oh, yes. Yes, absolutely. This delamination depends on the anisotropy of the material. Ordinary pieces of wood split, right? That's delamination between the cellulose fibers and the lignin in the wood. But something like titanium or stainless steel is not isotropic in that same way and, therefore, cracks do not form between foreign bodies, because they are all the same bodies within the material.

Q Is there anything individual about the PEEK material that can make the cracks present in this type of way?

A No. The only thing about the PEEK material is its anisotropy both in terms of its structure and its strength. So the strength is

maximum along the length of the fibers and it is minimal perpendicular to the fibers. So the cracks will always try to grow parallel to the fibers. And that's the delamination you're talking about.

Q Now, your report also indicates that the stripped screw hole is subjective of the fact that a very substantial force was used -- or rather was required to properly seek the placement bone.

MR. FULGINITI: Sorry, what page again?

Is it the bottom of Page 3 going on to 4?

MS. STUPNEVICH: Here we go. Page 4.

Paragraph that starts with "Microcracks."

BY MS. STUPNEVICH:

Q And on line 3, "Furthermore, the badly damaged and stripped screw hole indicates that a very substantial force was required to properly seat the plate on the bone."

A Yes.

Q Can you quantify for me the type of force or torque that you think would be required to properly seat the plate on the bone in this case?

A I know that the torque and the resulting force was not enough to embed the head of the screw into the plate. And so it wasn't excessive in the sense that the plate -- that it was over-torqued.

On the other hand, it was -- the torque was enough such that the screw, when it was inserted in the hole, was cross-threated in the hole. And as we know, if you cross-thread screws in holes, it takes more torque to put them in.

Q So is your position that the surgeon that implanted the plate did not utilize excessive force in -- during the implantation?

A I see no evidence of excessive force, because I think if there were excessive force the screw head would have been embedded in the plate in the same way that if one uses excessive force in screwing a -- putting in a screw into a piece of wood. The screw head will also embed into the wood. And I see no evidence of that.

Q Okay. As part of your preparation of this report, did you review the operative reports that were authored by the surgeon who performed Mr. Curry's implant surgery?

A I certainly reviewed his deposition and I reviewed parts of the operative reports, yes.

Q Okay. Is there anything in the report that suggests that either his technique was improper of that he had difficulty with trying to align the plate to the bone?

A I see no evidence of that. I think the terms were used that things were routine or whatever. There was no evidence that there was any difficulty.

Q So then explain to me what you mean when you say that the stripped screw indicates that a very substantial force was required to properly seat the plate on the bone.

A Well, like I said, when the threads are cross-threaded like that it takes more torque. But also in order to crack the plate in the way we see it, it requires a bending in the direction perpendicular to the length of the plate. And therefore it was sitting initially not flat on the bone and the side was pulled down to make contact.

Q But your position is that in order to pull it down a substantial or excessive force is not required?

A Certainly more than if it were not cross-threaded, if it were not pulled down. But it appears to me that the screw did not bury its head in the material and, therefore, it wasn't excessive in terms of what the material could tolerate.

Q Now, if the plate had fractured during the implantation, even if it was a partial fracture, is

this something that would have been immediately noticeable?

A Not necessarily, no. That's one of the problems with small cracks, is that the most dangerous cracks are the ones that exist that you don't know are there. So, no, you wouldn't necessarily see those.

Q Would it have necessarily made a sound if it wasn't visible?

A Not necessarily, no. Because this material is not like glass, where it would go ping or something like that. It's a much more ductile material.

Q But it's possible that it would have made a noise or a crack would have appeared immediately?

MR. FULGINITI: Objection to form.

THE WITNESS: I believe there were cracks. Whether they would have appeared immediately, whether they would have been visible to the people watching this procedure is quite another matter.

BY MS. STUPNEVICH:

Q Now, later on in your report you also indicate that the PEEK carbon fiber composite material is uniquely susceptible to cracking.

What's your basis for that opinion?

A This is the same thing that I was saying earlier. That one puts carbon fibers -- one puts fibers like for example fiberglass into a material to increase its strength in one direction. That's normally what is done. So you get a very good strength in one direction, but you pay for that with a very reduced strength in the perpendicular direction. That's why it's called anisotropic. So first of all, it has this great strength in one direction and no strength in the other. And the other thing is, and this is related to the fact that it's carbon fiber, and this compares to say a stainless steel plate, this plate cannot be conformed to the shape of the bone. I can't remember the terminology that the surgeons used, but they talk about using the stainless steel plate and essentially pre-deforming the plate to conform to the shape of the bone. That is absolutely impossible with a Carbofixed plate, because if you do that it will crack.

Q So there is a lot of information that you gave me. Let's unpack that a bit. With regards to the reduced strength in a perpendicular direction that you contend comes of this type of material

because strength is increased in the other direction, what testing have you done to make this determination that strength winds up being reduced in a different direction?

MR. FULGINITI: Objection to form.

THE WITNESS: The simplest experiment would be a split piece of wood. The wood splits along the grain. It doesn't split perpendicular to the grain for exactly that reason.

BY MS. STUPNEVICH:

Q So in your opinion the existence of those type of cracks in and of itself indicates that there is a reduced strength in that area?

A Oh, yes. Yes.

Q Now, did you yourself perform any type of test on this material to kind of gauge that opinion?

A No. I only observed the cracks and they exist in the predicted directions.

Q And, again, did you consult any literature pertaining to this theory as to the idea that strength is reduced in a perpendicular direction in the PEEK material?

A No. Only my general knowledge about such materials.

Q Okay. Now let's talk about what you said about the fact that the plate cannot be formed to conform to the shape of the bone. Are you saying that's the case for all carbon fiber plates?

A Yes.

Q What is your basis for that opinion?

A Because such a material cannot plastically deform without breaking the carbon fibers. The carbon fibers will deform very small. And in fact, even if you deform one of these plates until it totally fractures, it will only change its length by 2 percent or something like that. Whereas the stainless steel plate will deform by 20 percent. Much more.

Q In your opinion, is the carbon fiber composite PEEK material more flexible than stainless steel?

MR. FULGINITI: Objection to form.

THE WITNESS: It is less deformable and it is as rigid as stainless steel. That is to say it will not plastically deform, but it will elastically deform. So the two will elastically deform by the same amount with roughly the same forces. But the stainless steel, if you bend it with greater force it

will then change shape, whereas the carbon fiber plate will break.

BY MS. STUPNEVICH:

Q What tests have you done in between the two materials to compare that?

A I just know that as a material scientist. That's what I do for a living.

Q And can you cite any literature that states that?

A Oh, my goodness. I'm sorry, I'm not coming up with something. But it's any text on the deformation properties of materials would talk about that.

Q Okay. And you also indicate in your report, and this is in line that we were talking about, that the PEEK composite material has low tensile ductility?

A Yes. That's the same thing I talked about before, the 2 percent, yes.

Q In your opinion is the PEEK carbon fiber composite material plate appropriate for use in chronic nonunions as a general matter?

MR. FULGINITI: Objection to form.

THE WITNESS: I believe that the plate is appropriate for any application where cracks do

not become introduced into the material during installation. So if the plate can be put in position without exceeding the 2 percent deformation then it would be okay. But if it cannot be, then it would not be okay.

BY MS. STUPNEVICH:

Q Have you reviewed Mr. Curry's medical records, his X-rays, anything like that in this case?

A I've certainly read through them. There is a lot of jargon that I don't necessarily understand. But, yes, I've read them.

Q Do you believe that in this case the plate could have been put in the position that you're referring to where the cracks would not have formulated?

A I believe that it is almost -- it was most likely, almost certain, I would think, that the plate cracked, cracked not broken, but the plate cracked during insertion. And that was probably unavoidable.

Q Why do you say that was probably unavoidable?

A Because if it were avoidable they would have done it.

Q And do you think that it was unavoidable because of the nature of the chronic nonunion that Mr. Curry has?

MR. FULGINITI: Objection to form. He wasn't talking about a nonunion.

THE WITNESS: Yeah. I was trying to avoid the chronic nonunion, because I'm not sure that I totally understand all of that. But I was referring to the conformity between the plate and the bone.

BY MS. STUPNEVICH:

Q So let's talk about that. If we are trying to conform a plate to the bone, does the shape of the bone or does the existence of a bone not play a factor in how well or how poorly a plate can conform to it?

A The shape of the bone, yes, a great deal.

Q Is it fair to say if you have a bone that's extremely damaged, that will affect how well a plate conforms to it?

MR. FULGINITI: Objection to form "extremely damaged".

THE WITNESS: If the plate is damaged so that it has a shape that does not conform to the plate, then of course that is a problem.

BY MS. STUPNEVICH:

Q So the bone and its condition is something that affects how well a plate can conform to it, correct?

A Oh, yes. Yes. Whereas for a stainless steel plate, that's not the same problem. And as we know, stainless steel plates, plural, replaced this device.

Q In your opinion, I'm sorry if I've asked this before, do you believe that the use of this plate was inappropriate in Mr. Curry's specific case?

MR. FULGINITI: Objection to form.

THE WITNESS: Yes.

BY MS. STUPNEVICH:

Q Why do you say that?

A Because I believe that it was not possible to install the plate without deforming it to the extent that cracks were introduced into the plate.

Q And is that based on the condition of his bone that your -- what is your basis for saying that it was not possible to install the plate without deforming it?

A Well, because I believe that if it were possible that Dr. Suk and the Carbofix

representative would have found a way to do it such that it was not deformed.

Q Do you think that the condition of Mr. Curry's bone is something that would have affected whether or not it was possible to install the plate without deforming it?

MR. FULGINITI: Objection to form.

THE WITNESS: I think that that has everything to do with it.

BY MS. STUPNEVICH:

Q This type of plate with this type of material we have here, as a general matter, does it need to be bent during surgery?

A It needs to be bent a little bit almost always, as long as that bending is less than 2 percent strained. And that of course is said -- is stated in the literature and is not like a stainless steel plate.

Q Which would be bent greater?

A You could bend it more.

Q Got it. Do you know what type of hardware was utilized by Mr. Curry's surgeon to secure the plate?

A Yes. It was titanium six force screws.

Q Do you know if these were locking screws?

A They appear to be locking screws, just by the fact that they're threaded into the plate.

Q Now, with locking screws, the fact that they're screwed into a threaded hole, does that at all eliminate or lessen the need for the plate to be closely aligned with the bone?

A No.

Q Why not? Wouldn't the locking screws keep it in place once inserted into the thread hole?

A The locking screws lock the threads together, but if there is a gap between the plate and the hole and the bone, that gap has to be closed. And that has nothing to do with locking or non-locking screws.

Q You also indicate in your report that the main fracture occurred at a location of an abrupt change in curvature of the plate?

A Yes.

Q Which also coincides with a hole for the longest, most steeply inclined mounting screw. Do you remember that?

A Yes.

Q What is the significance of this, if any?

A At least three different things. One is that the -- if you think of the plate as being

somewhat spoon-shaped, then the place where the plate broke is in the most narrow portion of the handle of the spoon where it joins the bowl of the spoon. That's the first thing. The second thing is that the screw is -- at that point position is very highly inclined and, therefore, the locking threads gouge into the plate most severely when it's steeply inclined. And the third reason I can't remember right now.

Q Okay. What constitutes an abrupt change in curvature? How would you measure or define that? How does it compare to a slight change in curvature?

A Okay. Well, again referring to a spoon, spoon handles are almost never completely straight. They're gently curved and have more or less a constant curvature. But then when you come to the junction between the bowl of the spoon and the handle of the spoon, then the curvature changes very dramatically and it goes in the other direction. So right at that point you have that huge change in curvature.

Q So is any extent of curvature potentially problematic with a plate like this?

A No. It's not the curvature itself. It's the fact that this indicates the area where the

underlying bone undergoes that change of curvature and also where the bone has very high stress. That's the third point I was making, is that that change in the curvature is where the stresses are highest.

Q Okay. You said you reviewed some of Mr. Curry's medical records. Do you recall reviewing any images or any records that reference a black drainage that had come from the incision?

A A what?

Q Black drainage.

A Oh, yes. Yes.

Q In your opinion was this entirely the result of the plate failing?

A Certainly the black fibrous material contained within the drainage had to be from the fractured device.

Q Is there a possibility that maybe an infection contributed to this result or did it all look as though it had come from the plate?

MR. FULGINITI: Objection to form.

THE WITNESS: I don't pretend to be --

BY MS. STUPNEVICH:

Q Not from a medical standpoint. I mean based on your review and your knowledge of

materials.

MR. FULGINITI: Materials or inspections?

MS. STUPNEVICH: Materials.

MR. FULGINITI: He's answered that, but go ahead.

THE WITNESS: The pathology report referred to fibrous material that was removed from the wound area, and that's certainly from the plate.

BY MS. STUPNEVICH:

Q If the plate in this case was in fact fractured during the implantation, would you expect to see a widespread failure amongst a significant number of implants of this kind?

MR. FULGINITI: Objection to form.

THE WITNESS: I think the question is if this plate were cracked during installation and that led to the eventual failure would I expect that other plates would have been cracked during installation, therefore, would fail.

BY MS. STUPNEVICH:

Q Right.

A I don't know how many other similar installations there are, but I think that logic would tell you that both should be examined

carefully.

Q But looking at this type of a fracture and the tests you performed on the plate, the inspections that you've done, would you anticipate that with a plate of this nature you would see a lot of fracture incidents?

MR. FULGINITI: Objection to form.

THE WITNESS: If plates are installed in situations where you exceed the 2 percent ductility and induce cracks, that is very dangerous and very likely will form premature failures. I might add here that in engineering in general we assume that all structural devices contain cracks. And the question then is how big is the biggest possible crack and lets me know how big the biggest possible crack is, then we can calculate what is the highest, the biggest stress that we can apply to that. And that's the basis of the entire field of fracture mechanics.

BY MS. STUPNEVICH:

Q Makes sense. Dr. Pope, also you indicate in your report that there is no evidence of total fracture of the plate during installation, but partial cracking cannot be ruled out; is that

correct?

MR. FULGINITI: Where are you reading from?

MS. STUPNEVICH: I'm reading from Page 3.

BY MS. STUPNEVICH:

Q The paragraph that starts with, "This raises the question of whether," and if you go down to line 3, "near the fracture corresponds to the suture hole on the right side of the plate. There is no evidence of total fracture of the plate during installation, but partial cracking cannot be ruled out."

A That's correct.

Q Isn't it true that you also cannot conclusively rule out the possibility that partial cracking did not occur at the implant? So in other words, we can not say with certainty that this is when it happened?

MR. FULGINITI: Objection to form.

THE WITNESS: I can say with certainty that the cracks that were seen in the cross sectional views towards the end of my report on 37, 36 et cetera, those were definitely formed during installation. And other cracks close to the fracture surface, for example, the screw

that went into hole number 5 certainly produced cracks in that hole as well. So it is quite clear that there were preexisting cracks from the moment that this plate was installed.

BY MS. STUPNEVICH:

Q And this is -- I don't want to have you repeat what you told me during the course of your deposition, but this is based on your overview of the cracks and what they visually look like to you and your knowledge of the materials?

A Yes.

Q Can you conclusively rule out that those cracks that you reference specifically in 36 and 37 weren't caused by something like secondary trauma or just biological complications or something else?

MR. FULGINITI: Objection to form.

THE WITNESS: No. I see no other way that those cracks could have been formed except during the insertion of the screws.

BY MS. STUPNEVICH:

Q Okay. I think that might be all I have for you. Give me one second. I'll look through my notes.

MR. FULGINITI: Can we step out for a second?

MS. STUPNEVICH: Sure.

* * *

(Whereupon, a brief recess was taken.)

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MS. STUPNEVICH: That's all I have for you.

MR. FULGINITI: I have a couple questions.

E X A M I N A T I O N

BY MR. FULGINITI:

Q For the record, Ken Fulginiti. I represent Mr. Curry. I just want to be clear. With regard to the use of this plate with Mr. Curry, I want to make sure I understand. You're not saying that there was anything outwardly that would suggest to Dr. Suk that this was the wrong application, correct?

MR. FULGINITI: Objection to form.

THE WITNESS: Yeah. I think it's quite obvious that, of course, Dr. Suk thought it was the correct application, but also the company representative there didn't say anything that it was the wrong application. So I believe that, yes indeed, there was appeared outwardly to be the correct application of this plate.

BY MR. FULGINITI:

Q And I think what you were saying before is that the potential for complications here is whenever you have this greater than 2 percent number that you were talking about?

A Yes.

Q Okay. You're not in any way saying or suggesting that Dr. Suk misused the product or anything like that?

A No, I believe not. And again, it's because everything seemed to have gone smoothly, as they noted, and also the company representative was there and made no comments about misuse or anything like that.

Q And this 2 percent that you were talking about, I didn't see that anywhere in the instructions for use. Did you see that?

A No, it is not in there. It's only in the test results that are contained in the FDA information.

MR. FULGINITI: Okay. I have no further questions.

E X A M I N A T I O N

BY MS. STUPNEVICH:

Q Just one or two follow-up. When you say

that everything appeared outwardly to be correct for the application, what do you mean by that? Sorry. Let me clarify. During the procedure on Mr. Curry.

A Well, I conclude that based on the fact that first of all Dr. Suk said that things went smoothly and normally or something like that. But also there is no evidence that the Carbofix representative pointed out any difficulty or problem or made any statement that this should be done differently or whatever. So it appears as though both of those people thought it was okay.

Q But you're saying it's based solely on the operative report, I assume? You obviously weren't present during the procedure.

A No. Just --

MR. FULGINITI: Objection to form.

THE WITNESS: Just the information that we have available, yes.

BY MS. STUPNEVICH:

Q Okay. But as far as appearing outwardly to be the correct application, are you contending that Mr. Curry outwardly appeared to be an appropriate candidate for this plate?

A I believe that Mr. Curry's humerus appeared to be an appropriate place to use this

plate to Dr. Suk and to Mr. -- I forget his name already, but the company representative.

MS. STUPNEVICH: Okay. That's all I have for you.

MR. FULGINITI: A full-size transcript is fine.

MS. STUPNEVICH: I'd like an E-mailed transcript.

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(Witness excused.)

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(Whereupon, the deposition concluded at 12:55 p.m.)

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I N D E X

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WITNESS: David P. Pope, PH.D.

E X H I B I T S

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C E R T I F I C A T I O N

I, Karen A. Stevens, a Court Reporter and Notary Public, do hereby certify the foregoing to be a true and accurate transcript of the proceedings in this matter, as transcribed from the stenographic notes taken by me.

Karen A. Stevens
Court Reporter
Notary Public

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